



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,186	10/22/2003	John Girdner Atwood	07759-019004	6805

35411 7590 09/09/2005
KILYK & BOWERSOX, P.L.L.C.
3603 CHAIN BRIDGE ROAD
SUITE E
FAIRFAX, VA 22030

EXAMINER

BEISNER, WILLIAM H

ART UNIT PAPER NUMBER

1744

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/691,186

Applicant(s)

ATWOOD ET AL.

Examiner

William H. Beisner

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 219-257 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 219-222, 231-242 and 251-257 is/are rejected.
- 7) ☒ Claim(s) 223-230 and 243-250 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 8/31/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 8/31/2004 has been considered and made of record.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

Art Unit: 1744

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 219-222, 231-242 and 253-257 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dean et al.(WO 89/09437) in view of Van Nostrand (Van Nostrand's Scientific Encyclopedia).

With respect to claim 219, the reference of Dean et al. discloses an apparatus (10) that includes a heating and cooling system (12,14); a sample block (16) including at least one well (17). The sample block is capable of thermal contact with the heating and cooling system (12,14). The apparatus includes means for determining the temperature of the block (See pages 6-7 and element (22)). The apparatus includes a computing apparatus (See sub-housing (18) and page 5, line 24, to page 6, line 3) to control the heating and cooling system.

While the reference of Dean et al. discloses that "the microprocessor being programmed to anticipate the time lag between the support temperature and the reaction temperature if only the support is sensed" (See page 4) and the reference discloses the use of an algorithm for predicting the sample temperature based on the block temperature (See page 15), the reference is silent as to the specific algorithm employed to predict the sample temperature based on the block temperature.

The reference of Van Nostrand discloses a conventional algorithm (Newton's Law of Cooling, See page 1116) used to predict the temperature of a body as a function of time based on the temperature of a surrounding medium. The reference of Van Nostrand additionally discloses that the use of numerical integration is known in the art to solve a differential equation when

Art Unit: 1744

initial values are known (Euler Method for Numerical Solution of a Differential Equation, See page 620).

In view of the disclosure of the reference of Dean et al. to employ an algorithm to relate the temperature of the sample to that of the block temperature and in view of the algorithm and numerical integration disclosed by the reference of Van Nostrand, it would have been obvious to one of ordinary skill in the art to employ the temperature function of the reference of Van Nostrand to predict the temperature of the sample of the reference of Dean et al. for the known and expected result of employing an art recognized differential equation and numerical integration to predict the temperature of a body relative to the known temperature of another body which is required of the algorithm discussed of the reference of Dean et al. Note the algorithm recited in claims 219 is merely a numerical integration of the differential equation of the function disclosed by the reference of Van Nostrand which is conventional in the art.

With respect to claim 220, as discussed in the reference of Van Nostrand, one of ordinary skill in the art would recognize that the time constant is based on the size and material properties of the sample and block components.

With respect to the input device of claim 221, the reference of Dean et al. discloses the use of a keyboard as an input device (See pages 7 and 11).

Claims 239-241 are obvious over the combination of the references of Dean et al. and Van Nostrand for the same reasons set forth with respect to claims 219-221 above.

With respect to claims 222 and 242, while the reference of Dean et al. discloses a block (16) with wells (17), the reference is silent as to the specific dimensions of the wells.

Art Unit: 1744

However, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the size of the wells based merely on the desired size sample tubes intended to be used in the temperature control system.

With respect to the limitations of claims 231-238 and 251-257, while the reference of Dean et al. discloses that the device includes an input device (keyboard) and that the device is required to operate at a specific temperature/time profile, the reference is silent as to the specific various control parameters with respect to the temperature control in terms of overshoot, undershoot, tube size, sample volume, etc.

However, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art to determine the optimum control parameters to perform a desired PCR reaction based on considerations such as the specifics of the reaction to be performed in terms of the sample source and the reagents employed while maintaining the efficiency of the reaction system.

Allowable Subject Matter

6. Claims 223-230 and 243-250 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. The following is a statement of reasons for the indication of allowable subject matter:

With respect to claims 223-230 and 243-250, while the prior art of record discloses an automated system for controlling the temperature of a liquid sample which includes a sample block for holding the sample, a computer, heating and cooling control and a temperature measurement device for determining the temperature of the sample by sensing the temperature of the block, the prior art of record fails to teach or fairly suggest the claimed enclosure for the sample block which defines the recited central region, edge regions, manifold regions and manifolds.

Terminal Disclaimer

8. The terminal disclaimer filed on 6/22/2005 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patents 5,475,610 and 6,703,236 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Response to Arguments

9. Applicant's arguments, see page 19, section I, filed 6/22/05, with respect to consideration of the IDS filed 8/31/2004 have been fully considered and are persuasive. The IDS has been considered.

10. Applicant's amendments and associated arguments, see page 20, section II, filed 6/22/05, with respect to the computer program listing have been fully considered and are persuasive.

Art Unit: 1744

11. Applicant's amendments and associated arguments, see page 20, section III, filed 6/22/05, with respect to the specification have been fully considered and are persuasive.

12. Applicant's amendments and associated arguments, see pages 20-22, section IV, filed 6/22/05, with respect to the 35 USC 112, second paragraph, rejections have been fully considered and are persuasive.

13. Applicant's amendments and associated arguments, see page 22-23, sections V and VI, filed 6/22/05, with respect to the 35 USC 102 and 103 rejections over the reference of Dean et al. have been fully considered and are persuasive. In view of the amendments to the claims positively reciting the algorithm as part of the claimed device, a new ground of rejection has been made over the combination of the reference of Dean et al. and Van Nostrand.

14. Applicant's arguments, see pages 23-24, sections VII and VIII, filed 6/22/05, with respect to the obviousness-type double patenting rejections have been fully considered and are persuasive.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Dewdney (Am. J. Phys.) is cited as prior art that discloses that a cooling body obeys the same exponential equation as an RC circuit.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

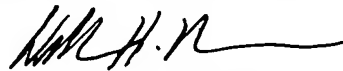
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1744

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



William H. Beisner
Primary Examiner
Art Unit 1744

WHB